

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated January 19, 2011 are respectfully requested.

I. Amendments

Claim 158 is amended to recite attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction to collectively form an opening adjacent the gastro-esophageal junction for receiving food from the esophagus and restricting the flow of the food into the stomach. Basis for these amendments can be found, for example, on page 16, lines 24-27 and page 38, lines 14-18 as well as in Figs. 10A-10B and 33D.

Claims 159, 163, 165, 170-171, and 176-177 are amended to conform language to the amendments to claim 158.

Claim 165 is further amended to improve readability.

Claims 159, 162-163, 167 and 176-177 are amended for proper dependency.

New claims 178 and 183 finds basis in previous claim 158.

New claim 179 finds basis, for example, on page 16, lines 24-26 and Fig. 10B.

New claims 180-182 find basis, for example, on page 38, lines 14-20.

No new matter is added by way of these amendments.

II. Rejections Under 35 U.S.C. § 102

Claims 158-163 and 175-177 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Deem et al. (U.S. Publication No. 2002/0183768, hereafter "Deem").

A. The Present Claims

Independent claim 158, as amended, is directed to a method of treating obesity in a patient comprising attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction to collectively form an opening adjacent the gastro-esophageal junction for receiving food from the esophagus and restricting the flow of the food into the stomach.

B. The Applied Art

Deem describes tools and methods for performing gastroplasty procedures (see ¶ [0001]). One variation involves fixing opposing interior walls of the stomach with a fastening element such as a staple to form a modified lumen along the length of the stomach (¶ [0021]). Another variation, shown in Figs. 37-39, involves creating an anastomosis between the stomach and the intestinal tract.

C. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

Deem fails to teach a method that includes attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction. Instead, Deem describes forming a “modified lumen” within the stomach by bringing the interior walls of the stomach together along the length of the stomach to form a smaller lumen and reduce stomach size (Fig. 5B). As seen in Fig. 4A, a single anchor is placed on either side of the esophagus and brought together (Fig. 4B) to form the modified lumen. Thus, at most two anchors are placed anywhere near the gastro-esophageal junction, which would not constitute a “plurality” as presently claimed.

Deem describes an additional procedure whereby an anastomosis is created between the stomach and the intestine (Fig. 38). However, in this embodiment, no anchors are placed anywhere near the gastro-esophageal junction.

Thus, Deem fails to teach each and every element of the present claims. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102.

III. Rejections Under 35 U.S.C. § 103

Claims 164-171 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Deem et al. in view of Orban, III et al. (U.S. Patent No. 7,744,627, hereafter “Orban”).

A. The Present Claims

The present claims are described above.

B. The Applied Art

Deem is described above.

Orban relates to the use of reinforcing lumen rings with a circular stapling instrument having a staple cartridge assembly and an anvil assembly (Abstract). In use, the anvil assembly is inserted into an end of a severed intestine and a purse string type suture is used to secure the intestine end to the anvil shaft. The staple cartridge assembly is separately inserted into the other severed intestine end and secured with a purse-string suture. The anvil shaft is operatively coupled to the staple assembly. The staple assembly is fired to secure the ends of the intestine as well as a reinforcing member positioned on the anvil, staple cartridge, or both.

C. Analysis

Determining obviousness under 35 U.S.C. § 103(a) requires an objective analysis involving four factual inquiries, which include:

- (a) determining the scope and content of the prior art,
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the art; and
- (d) evaluating evidence of secondary considerations.

See *Graham v. John Deere*, 383 US 17, 18, 148 USPQ 459, 467 (1966); see also M.P.E.P. § 2141.

To support an obviousness rejection, MPEP §2143.03 requires “all words of a claim to be considered” and MPEP § 2141.02 requires consideration of the “[claimed] invention and prior art as a whole.” A claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1385 (US 2007).

The Combination of Deem and Orban Fails to Provide an Articulated Reasoning to Support the Legal Conclusion of Obviousness

Even after *KSR*, it remains necessary to show “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. *KSR* at 418, citing *In re Kahn*, 441 F.3d 977, 988 (C.A. Fed. 2006). Further, the Office examination guidelines following the Court decision in *KSR* describe six rationales that may be used to support a rejection under 35 U.S.C. § 103. See Federal Register, Vol. 72, No. 195, October 10, 2007.

Here, the Examiner states “it would have been obvious to one having ordinary skill in the art...to have used a reinforcing material between tissue layers in the method of Deem et al. as suggested by Orban et al. to obtain the same advantages.” (paragraph 4 on page 3 of the Office action). This rejection appears to be relying on Rationale A - Combining Prior Art Elements According to Known Methods to Yield Predictable Results to support the rejection. A rejection based on this rationale must articulate: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination each element merely would have performed the same function as it did separately; (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and (4) whatever additional findings based on the Graham factual inquiries may be necessary to explain a conclusion of obviousness.

Here, the Examiner fails to articulate a finding that the prior art included each element claimed because the combination of prior art references does not show or suggest each element claimed.

As noted above, claim 158, from which 164-171 depend, relates to a method of treating obesity in a patient comprising the step of attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction to collectively form an opening adjacent the gastro-esophageal junction. The combination of Deem in view of Orban fails to show or suggest each of the features of the independent claim, and thus the rejected dependent claims.

As noted above, Deem fails to teach a method that includes attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction. While Orban does teach a reinforcing ring, the teaching in Orban is in reference to a circular stapler for creating an anastomosis in a tubular organ such as for a bowel resection. Orban makes no mention of coupling any implant in the stomach or esophagus, much less attaching a plurality of individual restrictor members as in the present claims.

One Skilled in the Art Would Not Modify Deem and Orban to Arrive at a Method as Presently Claimed

Based on the teaching of Deem and Orban, one skilled in the art looking to a method to treat obesity by modifications in the stomach would logically use the reinforcing ring of Orban with the anastomosis assembly of Deem in order to provide stability to the anastomosis lumen as taught by Orban. One skilled in the art might even use the reinforcing ring of Orban between overlapping tissue folds as in Fig. 6E of Deem to provide stability to the modified lumen. However, modification of Deem with Orban does not result in a method including attaching a plurality of individual restrictor members to the wall of the stomach adjacent the gastro-esophageal junction as presently claimed. In fact, attaching a plurality of individual restrictor members would at least make forming the modified lumen of Deem more difficult. Rather than attaching two anchors that can be drawn together to form the modified pouch, a plurality anchors would need to be attached and connected to each other. Further, having a plurality of anchors attached about the gastro-esophageal region would make the modified lumen lopsided as tissue would be drawn from a plurality of areas adjacent the gastro-esophageal junction rather than two. Nor would the step be effective for creating an anastomosis between the stomach and the intestine as the restrictors are placed too high (at the gastro-esophageal junction).

Accordingly, Applicants respectfully request withdrawal of the rejections over Deem in view of Orban.

IV. Conclusion

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-0700.

Respectfully submitted,
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Date: July 19, 2011

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